EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK

QAPP/FSP/SAP for: *(check appropriate box)* [ ] **GRANTEE** [X] **CONTRACTOR** [ ] **EPA** [ ] **Other**	**Entity** *(grantee, contract, EPA AO, EPA Program, Other)* Cadmus Group LLC	**Regulatory Authority and/or Funding Mechanism**	___ **2 CFR 1500 for Grantee/Cooperative Agreements** __X_ **48 CFR 46 for Contracts** ___ **Interagency Agreement (FFA, USGS)** ___ **EPA/Court Order** ___ **EPA Program Funding** ___ **EPA Program Regulation** ___ **EPA CIO 2105**
Document Title *[Note: Title will be repeated in Header]*	Support for Region 8 Underground Injection Control Dewey-Burdock Permitting Actions		
QAPP/FSP/SAP Preparer	Mary Ellen Tuccillo, The Cadmus Group LLC		
Period of Performance *(of QAPP/FSP/SAP)*	11/14/2018 to 6/30/2019	**Date Submitted for Review**	12/6/2018
EPA Project Officer **EPA Project Manager**	Nancy Parrotta, Project Officer Bruce Suchomel, Work Assignment Contracting Officer's Representative	**PO Phone #** **PM Phone #**	202-564-5260 303-312-6001
QA Program Reviewer or Approving Official	Bill Monson	**Date of Review**	12-14-18

Documents Submitted for QAPP Review **(QA Reviewer must complete):**

1. QA Document(s) submitted for review:

QA Document	Document Date	Document Stand-alone	Document with QAPP
QAPP	**12/6/2018**	Yes/No	
FSP		Yes/No	Yes/No
SAP		Yes/No	Yes/No
SOP(s)			Yes/No

2. WP/SOW/TO/PP/RP Date _____
WP/SOW/TO/RP Performance Period: 11/14/2018 – 6/30/2019

3. QA document consistent with the:
WP/SOW/PP for grants? No
SOW/TO for contracts? Yes

4. QARF signed by R8 QAM Yes
Funding Mechanism contract
Amount $5,814,344.00

Notes for Document Submittals:

1. A QAPP written by a Grantee, EPA, or Federal Partner must include for review: Work Plan(WP) / Statement of Work (SOW) / Program Plan (PP) / Research Proposal (RP) and funding mechanism
2. A QAPP written by Contractor must include for review:
   a) Copy of Task Order Work Assignment/SOW
   b) Reference to a hard or electronic copy of the contractor's approved QMP
   c) Copy of Contract SOW if no QMP has been approved
   d) Copy of EPA/Court Order, if applicable
   e) The QA Review must determine (with the EPA CO or PO) if a QARF was completed for the environmental data activity described in the QAPP.
3. a. Field Sampling Plan (FSP) and/or Sampling & Analyses Plan (SAP) must include the Project QAPP ***or*** must be a stand-alone QA document that contain all QAPP required elements (Project Management, Data Generation/Acquisition, Assessment and Oversight, and Data Validation and Usability).
   b. SOPs must be submitted with a QA document that contains all QAPP required elements.

Summary of Comments *(highlight significant concerns/issues)*: **The QAPP is approvable. The details of the project are outlined in the SOW. The SOW must be attached to the QAPP or included as an appendix.**

Support for Region 8 Underground Injection Control Dewey-Burdock Permit

1. No environmental samples are being collected under this QAPP. The QAPP addresses 2 unrelated projects that both use secondary data. Namely, 1) Conceptual Site reporting and groundwater modeling 2) Response to Comments. The QAPP adequately addresses the elements for project 1. The QAPP could be improved by including more specificity on the groundwater modeling software and it's accuracy criteria.
2. The Response to Comments project is an ongoing effort, this being part 3 of 3. Inorder to evaluate the 3rd part, a review of parts 1 and 2 would be necessary. Parts 1 and 2 were not provided. The QA review of parts 1 and 2 are beyond the scope of this review. Listed are the relevant policies and procedures. [HYPERLINK "https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf"]
   [HYPERLINK "https://www.epa.gov/dockets/commenting-epa-dockets"]
   https://www.epa.gov/sites/production/files/2016-03/documents/404q_factsheet.pdf

   I recommend the project following an orderly framework for the comments. Like the WOUS.

Clean Water Rule Comment Compendium
Topic 1: General Comments
Topic 2: Traditional Navigable Waters (TNWs), Interstate Waters,Territorial Seas, and Impoundments
Topic 3: Adjacent Waters
Topic 4: Other Waters
Topic 5: Significant Nexus
Topic 6: Ditches
Topic 7: Features and Waters Not Jurisdictional
Topic 8: Tributaries
Topic 9: Comments on Scientific Evidence Supporting Rule
Topic 10: Legal Analysis
Topic 11: Costs/Benefits (Volume 1)
Topic 11: Costs/Benefits (Volume 2)
Topic 12: Implementation Issues
Topic 13: Process Concerns and Administrative Requirements
Topic 14: Miscellaneous
Topic 17: Non-Technical Comments (Volume 1)

3. **The** Cadmus Group LLC **must address the comments in the Summary of Comments, as well as those identified in the Comment section(s) that includes a "Response (date)" and Resolved (date)".**

Element	Acceptable *Yes/No/NA*	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title	Y	2	Support for Region 8 Underground Injection Control Dewey-Burdock Permitting Actions

b. Date and revision number line (for when needed)	Y	2	EPA Contract No. EP-C-15-022 Version No. 0 Date: December 6, 2018
c. Indicates organization's name	Y	2	Organization Implementing the Project: The Cadmus Group LLC 100 5th Avenue, Suite 100 Waltham, MA 02451
d. Date and signature line for organization's project manager	Y	Separate page as a pdf	The signature page was saved as a pdf file containing the signature and date of the Cadmus Project Manager, Dr. Mary Ellen Tuccillo
e. Date and signature line for organization's QA manager	Y	Separate page as a pdf	The signature page was saved as a pdf file containing the signatures and dates of Dr. Karen Sklenar, QA Lead Reviewer and Richard Krop, Cadmus QA Officer, who signed for Donna Jensen, Contract QA Manager for The Cadmus Group LLC
f. Other date and signatures lines, as needed	Y	2 and on separate page saved as pdf	Bruce Suchomel, Work Assignment Contracting Officer's Representative Linda Himmelbauer, Region 8 Quality Assurance Director EPA Region 8 Nancy Parrotta, Project Officer EPA OGWDW, DWPD
A2. Table of Contents			
a. Lists QA Project Plan information sections	Y	3	
b. Document control information indicated	Y	3	
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization	Y	4	EPA and Cadmus staff
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors	Y	5	Dr. Mary Ellen Tuccillo, Manager Dr. Karen Sklenar, QA Lead Project Reviewer
b. Discusses their responsibilities	Y	5-6	
c. Project QA Manager position indicates independence from unit generating data	Y	6	[Dr. Karen Sklenar] has no direct operational function on the project, which preserves her independence in performing reviews of the products of this work assignment.
d. Identifies individual responsible for maintaining the official, approved QA Project Plan	Y	5	Dr. Tuccillo is responsible for maintaining the official, approved SQAPP
e. Organizational chart shows lines of authority and reporting responsibilities	Y	6	**Exhibit 1**
A5. Problem Definition/Background			

a. States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained	Y	7	Last four paragraphs under Section A5
b. Clearly explains the reason (site background or historical context) for initiating this project	Y	6-7	First three paragraphs under Section A.5
c. Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project	Y	6	First paragraph references regulations applicable to the EPA permitting actions. The Cadmus work is not subject to any regulatory criteria or action limits. However, the EPA will use Cadmus's work to fulfil applicable UIC regulations referenced in this section.
A6. Project/Task Description			
a. Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals	Y	7-8	Task 1: p. 7-8 Task 2: p. 8 (although no QA requirements triggered for these tasks) Task 3: p. 8
b. Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments	Y	Added as Appendix B.	
c. Details geographical locations to be studied, including maps where possible	N/A		There is no field work involved for this WA. Although the study location is the Dewey-Burdock ISR project site, the literature review tasks are not tied to a particular geographic site and the response to comments tasks are not tied to any specific physical locations at the project site.
d. Discusses resource and time constraints, if applicable	N/A		
A7. Quality Objectives and Criteria			
a. Identifies - performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, - including project action limits and laboratory detection limits and - range of anticipated concentrations of each parameter of interest	Y	9-10	Cadmus identifies the type of secondary data that are expected to be reviewed, identifies applicable quality criteria and how the criteria will be applied. Cadmus also explains how data quality will be documented in the deliverables.
b. Discusses precision	Y	11	Explanation included as to how the concept of precision applies and will be addressed.
c. Addresses bias	Y	11	Explanation included as to how the concept of bias applies and will be addressed.
d. Discusses representativeness	Y	12	Explanation included as to how the concept of representativeness applies and will be addressed.
e. Identifies the need for completeness	Y	11-12	Explanation included as to how completeness applies and will be addressed.

f. Describes the need for comparability	Y	12-13	Explanation provided that comparability issues do not apply to the tasks described.
g. Discusses desired method sensitivity	Y	13	Explanation included as to how completeness applies and will be addressed.
A8. Special Training/Certifications			
a. Identifies any project personnel specialized training or certifications	Y	13	No special training or certifications are required for this project. The professionals selected by Cadmus to support this work assignment have the necessary understanding of UIC program requirements and technical background to perform the tasks described.
b. Discusses how this training will be provided	N/A		No special training or certifications are required for this project
c. Indicates personnel responsible for assuring training/certifications are satisfied	N/A		No special training or certifications are required for this project
d. identifies where this information is documented	N/A		Because there are no special training or certifications required for this project, there is no need to track and document this information.
A9. Documentation and Records			
a. Identifies report format and summarizes all data report package information	Y	13	A9.1 Documentation and Records of Data Quality Information
b. Lists all other project documents, records, and electronic files that will be produced	Y	14	A9.2 Documentation and Records of Work Assignment Deliverables
c. Identifies where project information should be kept and for how long	Y	14	Under *A9.2 Documentation and Records of Work Assignment Deliverables*
d. Discusses back up plans for records stored electronically	Y	14	Under *A9.2 Documentation and Records of Work Assignment Deliverables*
e. States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individual responsible for this	Y	13	First paragraph
B. Data Generation/Acquisition			
B1. Sampling Process Design (Experimental Design)			
a. Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample	NA	15	
b. Details the type and total number of sample types/matrix or test runs/trials expected and needed	NA	15	
c. Indicates where samples should be taken, how sites will be identified/located	NA	15	
d. Discusses what to do if sampling sites become inaccessible	NA	15	

e. Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.	NA	15	
f. Specifies what information is critical and what is for informational purposes only	NA	15	
g. Identifies sources of variability and how this variability should be reconciled with project information	NA	15	
B2. Sampling Methods			
a. Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken	NA	15	
b. Indicates how each sample/matrix type should be collected	NA	15	
c. If in situ monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data	NA	15	
d. If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages	NA	15	
e. Indicates how samples are to be homogenized, composited, split, or filtered, if needed	NA	15	
f. Indicates what sample containers and sample volumes should be used	NA	15	
g. Identifies whether samples should be preserved and indicates methods that should be followed	NA	15	
h. Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of	NA	15	
i. Identifies any equipment and support facilities needed	NA	15	
j. Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented	NA	15	
B3. Sample Handling and Custody			
a. States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for in-situ or continuous monitoring, the maximum time before retrieval of information	NA	15	

b. Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)	NA	15	
c. Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible	NA	15	
d. Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan	NA	15	
e. Identifies chain-of-custody procedures and includes form to track custody	NA	15	
B4. Analytical Methods			
a. Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures	NA	15	
b. Identifies equipment or instrumentation needed	NA	15	
c. Specifies any specific method performance criteria	NA	15	
d. Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation	NA	15	
e. Identifies sample disposal procedures	NA	15	
f. Specifies laboratory turnaround times needed	NA	15	
g. Provides method validation information and SOPs for nonstandard methods	NA	15	
B5. Quality Control			
a. For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency	NA	15	
b. Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented	NA	15	

c. Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data	NA	15	
B6. Instrument/Equipment Testing, Inspection, and Maintenance			
a. Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this	NA	15	
b. Identifies testing criteria	NA	15	
c. Notes availability and location of spare parts	NA	15	
d. Indicates procedures in place for inspecting equipment before usage	NA	15	
e. Identifies individual(s) responsible for testing, inspection and maintenance	NA	15	
f. Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented	NA	15	
B7. Instrument/Equipment Calibration and Frequency			
a. Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration	NA	15	
b. Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment	NA	15	
c. Identifies how deficiencies should be resolved and documented	NA	15	
B8. Inspection/Acceptance for Supplies and Consumables			
a. Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials	NA	15	
b. Identifies the individual(s) responsible for this	NA	15	
B9. Use of Existing Data (Non-direct Measurements)			
a. Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used	Y	16	First full paragraph
b. Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project	Y	16	First full paragraph

c. Indicates the acceptance criteria for these data sources and/or models	Y	17	Last paragraph. Rather than defined acceptance criteria, Cadmus will provide the EPA with information about any limitations of data sources used to the develop the model criteria.
d. Identifies key resources/support facilities needed	NA		Work involves technical review publicly available technical documents, guidance documents or reference information provided by EPA. No support facilities or unusual key resources are required.
e. Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing	NA		
B10. Data Management			
a. Describes data management scheme from field to final use and storage	Y	18-20	
b. Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs	Y	19	**B10.4 Data Tracking and Storage**
c. Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately	Y	16	**B10.2 Data Transmittal**
d. Identifies individual(s) responsible for this	Y	18	First paragraph under **B10. Data Management**
e. Describes the process for data archival and retrieval	NA		There will be no need to archive the data.
f. Describes procedures to demonstrate acceptability of hardware and software configurations	Y	19-20	Data storage security and backup system are described.
g. Attaches checklists and forms that should be used	NA		
C. Assessment and Oversight			
C1. Assessments and Response Actions			
a. Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates	NA		Assessment of quality of secondary data sources will be done at the time the data is reviewed, so there is no need to track number and frequency of this assessment.
b. Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process	21		Fourth paragraph
c. Describes how and to whom assessment information should be reported	21		Fourth paragraph
d. Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented	NA		Quality of data sources will be documented, but corrective action is not applicable to use secondary data.

C2. Reports to Management			
a. Identifies what project QA status reports are needed and how frequently	Y	21	Monthly progress reports to the EPA
b. Identifies who should write these reports and who should receive this information	Y	21	Second paragraph under this section.
D. Data Validation and Usability			
D1. Data Review, Verification, and Validation			
Describes criteria that should be used for accepting, rejecting, or qualifying project data	Y	22	
D2. Verification and Validation Methods			
a. Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any	Y	23	Second to last paragraph: Cadmus will document data sources in terms of EPA's Assessment Factors (see Section B9) for those data sources that rank as citable.
b. Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.	Y	23	Last paragraph
c. Identifies issue resolution process, and method and individual responsible for conveying these results to data users	NA		In general, if a data source does not meet EPA's Assessment Factors, it will not be used as a citable source. If the source is used anyway, because it provides unique information applicable to a criterion Cadmus determined is necessary for model development, the data quality limitations will be documented.
d. Attaches checklists, forms, and calculations	NA		
D3. Reconciliation with User Requirements			
a. Describes procedures to evaluate the uncertainty of the validated data	Y	24	
b. Describes how limitations on data use should be reported to the data users	Y	24	